JUL 1 1 2001

K003551

SUMMARY OF SAFETY AND EFFECTIVENESS

510(k) SUMMARY

COMPANY NAME AND CONTACT PERSON

May 03, 2001

Jostra AG
Hechinger Straße 38
72145 Hirrlingen
Germany

Kathleen Johnson, Regulatory Affairs Manager
phone 610 932 7738

DEVICE NAME

Venous Hardshell Cardiotomy Reservoir

COMMON NAME

Blood Reservoir

CLASSIFICATION NAME

Cardiopulmonary bypass blood reservoir (21 CFR – 870.4400)
Cardiopulmonary bypass defoamer (21 CFR – 870.4230)
Cardiopulmonary bypass cardiotomy suction line blood filter (21 CFR – 870.4270)

PREDICATE DEVICE OR LEGALLY MARKETED DEVICE

Bentley HSR 4000 Hardshell Venous Reservoir with Cardiotomy Autotransfusion Filter (K915573)
Venous Hardshell Cardiotomy Reservoir VHK 4200, Jostra AG (K982136)
Bentley Filtered Venous Reservoir BMR 4500S, Edwards Lifesciences (K974155)

DEVICE DESCRIPTION

The Jostra Venous Hardshell Cardiotomy Reservoir VHK 4201 is a sealed venous reservoir with integrated cardiotomy filter and pressure relief valve. The reservoir's filtration unit is divided into two zones. In the lower, venous area, the venous blood flowing from the patient is passed through a de-foamer filter, directly into the standing blood reservoir. An integrated siphon at the end of the venous inlet prevents air from rising. In the upper part of

of the filtration unit, suction blood is collected and passed through a de-foamer and filter. The filter has a pore size of 40 µm.
With a capacity of 4200 ml, the reservoir meets the requirements of all common operation techniques in the field of open-heart surgery. The computer optimized blood pathreduces the shear forces affecting the blood and avoids turbulence which is damaging to the blood.

INTENDED USE

The Venous Hardshell Cardiotomy Reservoir VHK 4201 is indicated for use to collect, store, filter and defoam the blood in an extracorporeal perfusion circuit for CPB with or without vacuum assisted venous return up to six hours. In addition, the reservoir is to be used post-operatively as an autotransfusion reservoir to return autologous blood shed from the chest to the patient for volume replacement.

TECHNOLOGICAL CHARACTERISTICS

Name of the Product	Venous Hardshell Cardiotomy Reservoir VHK 4200 (Jostra AG)	Venous Hardshell Cardiotomy Reservoir VHK 4201 (Jostra AG)	BMR 4500S Filtered Venous Reservoir (Jostra-Bentley)	HSR 4000 Venous Reservoir with Autotransfusion Filter (Jostra-Bentley)
Venous Blood Flow	max. 7 LPM	max. 7 LPM	1-7 LPM	1-7 LPM
Cardiotomy Blood Flow	max. 5 LPM	max. 5 LPM	max. 5 LPM	max. 5 LPM
Combined Flow	max. 7 LPM	max. 7 LPM	max. 7 LPM	max. 7 LPM
Minimum operating volume	500 ml	500 ml	200 ml	300 ml
Maximum volume capacity	4200 ml	4200 ml	4500 ml	4500 ml
Defoamer agent	Silicone Antifoam	Silicone Antifoam	Silicone Antifoam	Silicone Antifoam
Venous Defoamer	Polyurethane foam	Polyurethane foam	Polyurethane foam/ polyester	Polyurethane foam/ polyester
Cardiotomy filter	Polyester	Polyester	Polyester	Polyester
Pore size cardiotomy filter	40 microns	40 microns	20 microns	20 microns
Housing material	polycarbonate	polycarbonate	polycarbonate	polycarbonate
Sealing	unsealed	sealed	sealed	sealed
Pressure relief valve	no	yes	separate	yes
Temperature probe	yes	yes	yes	no
Venous inlet connector	½"	½"	½"	½"
Cardiotomy inlets	Seven total: six ¼"; one 3/8"	Seven total: six ¼"; one 3/8"	Five total: two ¼"; two ¼"x3/8"; one 3/8"	Four total: two ¼"; two ¼" x 3/8"
Recirculation	¼"	¼"	¼"	¼"
Venous sampling port	Female Luer-Lock	Female Luer-Lock	Luer Ports	½" connector
Blood outlet connector	3/8"	3/8"	3/8"	3/8"
Quick Prime Connector	¼"	¼"	¼"	3/8"
Vent port	¼"	¼"	¼"	¼"

SAFETY TESTING

Biocompatibility and Blood Cell Damage:

Biocompatibility testing of the Venous Hardshell Cardiotomy Reservoir VHK 4201 was performed in accordance with the FDA Blue Book Memorandum - #G95-1 and Biological Evaluation of Medical Devices Guidance – International Standard ISO 10993-1, and in accordance with United States Pharmacopeia – XXIII.

Based on the results of the biocompatibility testing performed, Venous Hardshell Cardiotomy Reservoir VHK 4201 was determined to be biocompatible and nontoxic, therefore, safe for its intended use.

Blood cell damage testing of the Venous Hardshell Cardiotomy Reservoir VHK 4201 has been performed by utilizing heparinized human whole blood circulated at specified constant flow rates for a six hour period compared to the predicate device.

Sterility:

Sterilization of the Venous Hardshell Cardiotomy Reservoir VHK 4201 has been validated to assure a sterility assurance level (SAL) of 10^{-6}.

EtO sterilized Venous Hardshell Cardiotomy Reservoir VHK 4201 are according to Federal Register , Vol. 43, No. 122 – Friday, June 23, 1978.

EtO Residuals:

Venous Hardshell Cardiotomy Reservoir VHK 4201 meets the limits for residual concentrations of ethylene oxide (<25 ppm), ethylene chlorohydrin (<25 ppm), and ethylene glycol (< 250 ppm) as published in Federal Register , Vol. 43, No. 122 – Friday, June 23, 1978.

Pyrogens:

Routine Pyrogen Testing is performed using the Limulus Amebocyte Lysate (LAL) method. Product testing and release criteria (less than 20 EU/ml) is in accordance to the December 1987 Guideline issued by the Food and Drug Administration, office of Compliance („Guideline on Validation of the Limulus Amebocyte Lysate Test as an End-Product Endotoxin Test for Human and Animal Parenteral Drugs, Biological Products, and Medical Devices").

EFFECTIVENESS TESTING

Function of the Venous Hardshell Cardiotomy Reservoir VHK 4201 was determined by evaluating its operational characteristics.

Conclusion

Function, sterility and biocompatibility testing demonstrated that the Venous Hardshell Cardiotomy Reservoir VHK 4201, when compared to the Predicate Devices Bentley Hardshell Venous Reservoir HSR 4000, the Jostra Venous Hardshell Cardiotomy Reservoir VHK 4200 and the Bentley Filtered Venous Reservoir BMR 4500S , does not significantly affect safety and effectiveness and thus is substantially equivalent to the Bentley Hardshell Venous Reservoir HSR 4000, the Venous Hardshell Cardiotomy Reservoir VHK 4200 and to the Bentley Filtered Venous Reservoir BMR 4500S.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 11 2001

Jostra® AG
Ms Kathleen Johnson
Regulatory Affairs manager
c/o Jostra Bently Corp.
17511 Armstrong Ave
Irvine, CA 92614

Re: K003551
Trade Name: Venous Hardshell Cardiotomy Reservoir, Model VHK 4201
Regulation Number: 870.4400 and 870.4230
Regulatory Class: II (Two)
Product Code: DTN and DTP
Dated: May 1, 2001
Received: May 9, 2001

Dear Ms. Johnson:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might

have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

510(k) Number: K003551

Device Name: Venous Hardshell Cardiotomy Reservoir VHK 4201

Indications for Use Venous Hardshell Cardiotomy Reservoir VHK 4201
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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 3-10-98)

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